

SUMMARY OF SAFETY AND EFFECTIVENESS

1. Name of Manufacturer

TechLab, Inc.
Corporate Research Center
1861 Pratt Drive
Blacksburg, VA 24060

K 955897

AUG - 5 1996

2. Establishment Registration

Federal ID # 54-1527427
Initial Registration of Medical Device Establishment, #1122855

3. Trade Name

Crypto/Giardia-Cel IF Test

4. Common Name

Cryptosporidium and *Giardia* Immunofluorescent Test

5. Class of Device

This device is classified in Class I.

6. Performance Standards

No performance standards have been developed for this device under 514 of the Food, Drug, and Cosmetic Act.

7. Safety and Effectiveness

The TechLab *Crypto/Giardia*-Cel IF Test can be used to detect *Cryptosporidium* oocysts and *Giardia* cysts in fecal specimens from persons suspected of having intestinal disease due to these pathogens. The kit, which includes ready-to-use reagents, contains an antibody reagent consisting of a mixture of FITC-labeled anti-*Cryptosporidium* monoclonal antibody and FITC-labeled anti-*Giardia* monoclonal antibody. These antibodies function as the detecting antibodies. The monoclonal antibodies are prepared from mouse ascites fluid. The antibodies against *Giardia* are the same as those used in the *Giardia*-Cel IF Test (K912152), which has been cleared for in vitro diagnostic use.

The *Crypto/Giardia*-Cel IF Test is to be used in an immunofluorescent assay and is substantially equivalent to an approved immunofluorescent test that also is specific for *Cryptosporidium* and *Giardia*. Both of these tests serve as diagnostic aids for cryptosporidiosis and giardiasis by detecting the organism or its antigens.

The TechLab *Crypto/Giardia*-Cel IF Test was compared in two studies with the Merifluor *Cryptosporidium/Giardia* Direct Immunofluorescent Detection Procedure (Meridian Diagnostics, Inc., Cincinnati, OH) for the detection of these organisms in fecal specimens. In addition, the TechLab test was compared in one of the studies with the *Giardia*-Cel IF Test, which has been approved for in vitro diagnostic use, and with the *Crypto*-Cel IF Test, for which we have submitted a 510(k) application. The results of our clinical evaluations show that the TechLab *Crypto/Giardia*-Cel IF Test exhibits a correlation of 100% when compared with these tests. These results show that the TechLab *Crypto/Giardia*-Cel IF Test is useful for the detection of these pathogens in fecal specimens.